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Beyond Compliance

How to Align with USFDA, MHRA & EMA Expectations

A practical guide for CROs & Sponsors

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The Reality

Global regulators are raising expectations.

Compliance is no longer document-based
it’s system-based, risk-based, and evidence-driven.

If you plan to work with global sponsors,
alignment is not optional.

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Build a Strong QMS Foundation

Regulators expect:

- Clear SOP hierarchy
- Defined roles & responsibilities
- Document control system
- Change management process
- Deviation & CAPA framework

No fragmented systems. No informal processes.

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Implement Risk-Based Quality Management

USFDA, MHRA & EMA emphasize:

- Risk assessment before study start
- Critical data & process identification
- Ongoing risk review
- Documented mitigation plans

Risk management must be proactive not reactive.

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Ensure Data Integrity

Inspectors focus heavily on:

- ALCOA+ principles
- Audit trails
- Access controls
- Source data verification
- Electronic system validation

If it isn’t traceable, it doesn’t exist.

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Strengthen Oversight & Vendor Control

Regulators expect sponsors & CROs to:

- Qualify vendors formally
- Define oversight plans
- Review monitoring reports
- Maintain accountability

Delegation does not remove responsibility.

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Maintain Continuous Inspection Readiness

Alignment means:

- Internal audits
- Mock inspections
- Staff training records
- Updated SOPs
- Readily retrievable documentation

Inspection readiness is a culture not an event.

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Global alignment isn’t about copying guidelines. It’s about embedding compliance into daily operations.

That’s what regulators actually assess.

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